

MAR 15 2006

Summary of Safety and Effectiveness
Howmedica Osteonics® Modular Rotating Hinge Knee with Offset Adapters

Proprietary Name:	Howmedica Osteonics® Modular Rotating Hinge Knee with Offset Adapters
Common Name:	Modular Rotating Hinge Knee
Classification Name and Reference	Knee joint femorotibial metal/polymer constrained cemented prosthesis, 21 CFR §888.3510
Device Product Code:	87 KRO
For Information contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	February 9, 2006

Description:

This Special 510(k) submission is a line extension intended to add offset adapters to the Howmedica Osteonics® Modular Rotating Hinge Knee.

Intended Use:

The combination of the predicate systems as cleared in the Howmedica Osteonics® Modular Rotating Hinge Knee and Howmedica Total Stabilizer Knee Components 510(k) premarket notifications does not alter the intended use. The subject and predicate devices are single use, sterile knee replacement systems. The indications for use for the Howmedica Osteonics® Modular Rotating Hinge Knee with Offset Adapters are provided below.

Indications for Use:

The Modular Rotating Hinge Knee is intended to be implanted with bone cement for the following conditions:

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.

- The ligaments are inadequate and/or the musculature is weak.
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

Substantial Equivalence:

The subject Howmedica Osteonics® Modular Rotating Hinge Knee with Offset Adapters share the same design, intended use, performance, materials, and operational principle as that of the currently available Howmedica Osteonics® Modular Rotating Hinge Knee and Howmedica Total Stabilizer Knee Components. An engineering analysis demonstrated comparable mechanical properties to the predicate components and substantial equivalence to these devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Howmedica Osteonics Corp.
C/o Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K060360

Trade/Device Name: Howmedica Osteonics Modular Rotating Hinge Knee with Offset
Adapters

Regulation Number: 21 CFR 888.3510

Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis

Regulatory Class: Class II

Product Code: KRO

Dated: February 9, 2006

Received: February 13, 2006

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

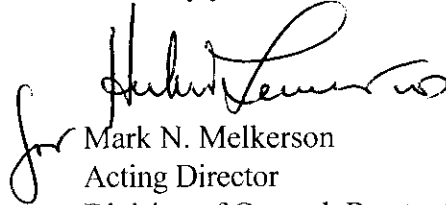
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a large, stylized "for" that is part of the typed name below.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060360

510(k) Number (if known):

Device Name: Howmedica Osteonics® Modular Rotating Hinge Knee with Offset Adapters

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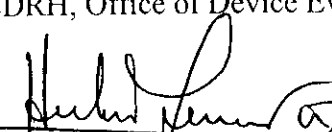
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060360